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(54) Title: USE OF AZITHROMYCIN FOR THE MANUFACTURE OF A MEDICAMENT FOR TREATMENT OF NON-INFECTION INFLAMMATORY DISEASES

(57) Abstract: The invention relates to the use of 9-deoxy-9-dihydro-9a-methyl-9a-aza-9a-homoerythromycin. A (generic name: azithromycin) for the therapy of neutrophil-dominated non-infective inflammatory diseases, pharmaceutical compositions containing azithromycin for enteral or parenteral administration and methods for the production of these pharmaceutical compositions.

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A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K31/7048 A61P1/00
A61P37/00

A61P11/00

A61P17/00

A61P29/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K A61P

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

WPI Data, EPO-Internal, PAJ, BIOSIS, PASCAL, EMBASE, MEDLINE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>RUBIN B.K. ET AL: "Macrolide antibiotics as biological response modifiers." CURRENT OPINION IN INVESTIGATIONAL DRUGS, (2000) 1/2 (169-172). , XP001104803</p> <p>abstract</p> <p>page 169, column 2, paragraphs 2,3,5</p> <p>page 170, column 1, paragraphs 2,3</p> <p>page 170, column 2, paragraph 3</p> <p>page 171, column 1, paragraph 4</p> <p>---</p> <p style="text-align: center;">-/--</p>	1-6, 43-45, 54-56



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
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- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>NARITA NOBUHIRO: " "Multi-effect" macrolides." INTERNAL MEDICINE (TOKYO), vol. 39, no. 8, August 2000 (2000-08), pages 599-600, XP001104921 ISSN: 0918-2918 page 599, left-hand column, paragraph 1 page 599, right-hand column, line 4,5</p> <p>---</p> <p>SCAGLIONE F ET AL: "Comparative anti-inflammatory effects of roxithromycin, azithromycin and clarithromycin." JOURNAL OF ANTIMICROBIAL CHEMOTHERAPY, vol. 41, no. SUPPL. B, March 1998 (1998-03), pages 47-50, XP001104919 ISSN: 0305-7453 abstract page 47, left-hand column, paragraphs 1,2 'Discussion'</p> <p>---</p> <p>LABRO M.T. ET AL: "Immunomodulation by macrolide antibiotics." JOURNAL OF CHEMOTHERAPY, (2001) 13/1 (3-8). , XP001104982 abstract 'Introduction' page 4, right-hand column figure 2 page 5, right-hand column, paragraph 1 page 7, right-hand column, line 17 - line 25</p> <p>---</p> <p>DATABASE MEDLINE 'Online!' December 2000 (2000-12)</p> <p>GÓMEZ J ET AL: "'Prospective, comparative study (1994-1998) of the influence of short-term prophylactic treatment with azithromycin on patients with advanced COPD!'" Database accession no. NLM11498704 XP002213965 abstract & REVISTA ESPANOLA DE QUIMIOTERAPIA: PUBLICACION OFICIAL DE LA SOCIEDAD ESPANOLA DE QUIMIOTERAPIA. SPAIN DEC 2000, vol. 13, no. 4, December 2000 (2000-12), pages 379-383, ISSN: 0214-3429</p> <p>---</p>	1,2,21, 45,54
X		1,2,45, 54
X		1-4,6, 45,54
X		1,2, 21-25, 45,54

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	ALTSCHULER E.L.: "Azithromycin, the multidrug-resistant protein, and cystic fibrosis '4!.' LANCET, (25 APR 1998) 351/9111 (1286). , XP001105350 paragraph '0001! --- SETHI G.R. ET AL: "Bronchiectasis: Causes and management." INDIAN JOURNAL OF PEDIATRICS, (2000) 67/2 (133-139). , XP001105351 abstract page 137, 'Role of Antibiotics' --- WALES D. ET AL: "The anti-inflammatory effects of macrolides." THORAX, (1999) 54/SUPPL. 2 (S58-S62). , XP001104995 page 559, right-hand column; table 1 page 560, left-hand column, paragraph 2 table 3 page 560, right-hand column, line 45-47 page 561, right-hand column, line 13 - line 18 page 561, right-hand column, line 25 - line 29 'Learning Point' 2 --- SPENCER D.: "Macrolide antibiotics in diffuse panbronchiolitis and in cystic fibrosis '2!.' EUROPEAN RESPIRATORY JOURNAL, (1998) 11/6 (1428). , XP001104988 the whole document --- DESTACHE CHRISTOPHER J ET AL: "Clinical and economic considerations in the treatment of acute exacerbations of chronic bronchitis." JOURNAL OF ANTIMICROBIAL CHEMOTHERAPY, vol. 43, no. SUPPL. 1, March 1999 (1999-03), pages 107-113, XP001104994 ISSN: 0305-7453 abstract 'Discussion', first and last paragraph ---	1,2,21, 45,54 1,2,21, 43,45, 54,55 1,2,21, 45,54 1,2,21, 45,54 1,2,21, 45,54 1,2,21, 45,54
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C(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FERNANDEZ-OBREGON, A. C.: "Azithromycin for the treatment of acne" INT.J. DERMATOL., vol. 39, 2000, pages 45-50, XP002213964 abstract page 45, left-hand column, line 10 - line 13 page 46, left-hand column, line 16 - line 17; table 2 page 46, right-hand column, line 17 - line 22 page 47, right-hand column, line 9 - line 11 'Discussion' ----	1, 3, 21-25, 45, 54
X	WO 99 24036 A (ORMEROD ANTHONY DAVID ;UNIV ABERDEEN (GB); WINFIELD ARTHUR (GB)) 20 May 1999 (1999-05-20) claims 3,7,8 ----	1, 3, 21, 45, 54
X	DATABASE EMBASE 'Online! ELSEVIER SCIENCE PUBLISHERS, AMSTERDAM, NL; MOMIN A. ET AL: "Reiter's syndrome - 3 case report." retrieved from STN Database accession no. 1998054754 XP002213966 abstract & BANGLADESH JOURNAL OF DERMATOLOGY, VENEREOLGY AND LEPROLOGY, (1997) 14/2 (49-53). , ----	1, 3, 21, 45, 54
X	O'DELL J.R.: "Is there a role for antibiotics in the treatment of patients with rheumatoid arthritis?." DRUGS, (1999) 57/3 (279-282). , XP001104987 '4. Other Antimicrobials' ----	1, 4, 6, 21, 45, 54
X	GUI G. P. H. ET AL: "Two-year-outcomes analysis of Crohn's disease treated with rifabutin and macrolide antibiotics" JOURNAL OF ANTIMICROBIAL CHEMOTHERAPY, (1997), 39(3), 393-400, 47 REFS. ISSN: 0305-7453 CODEN: JACHDX, XP001104989 University Department of Surgery, St George's Hospital Medical School, Cranmer Terrace, London SW17 ORE, United Kingdom abstract page 394, right-hand column, paragraph 1 page 398, left-hand column, line 13 - line 15 ----	1, 4, 5, 21-26, 43-45, 54-56

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 00 25756 A (OTTERBECK NORBERT ;KIST MANFRED (DE); FALK PHARMA GMBH (DE)) 11 May 2000 (2000-05-11) abstract page 3, paragraph 2 page 5, paragraph 3 page 6, paragraph 2 -page 7, paragraph 1 page 9, paragraph 5 -page 10, paragraph 1 page 13, table claims 1,8,9,17-20,28,29,32,40-42 ----	1,4,5, 7-33, 45-54
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A	page 2, line 21 - line 23 page 2, line 30 - line 44 claims 2,3,5,8-10,16-23 ----	11-14
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A	page 1, line 1 page 6, line 13 page 7, line 13,14,29,30 page 8, line 27 - line 30 page 11, line 9 - line 15 ----	9,10, 16-20
X	WO 95 09601 A (PROCTER & GAMBLE) 13 April 1995 (1995-04-13)	45,51-54
A	page 4, line 14 - line 16 ----	16-20

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Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
- No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 2; 1 and 7-58 (partly)

Use of a pharmaceutical composition comprising azithromycin or derivatives thereof for the manufacture of a medicament for the treatment of neutrophil-dominated, non-infective inflammatory pulmonary disease.

2. Claims: 3; 1 and 7-58 (partly)

Use of a pharmaceutical composition comprising azithromycin or derivatives thereof for the manufacture of a medicament for the treatment of neutrophil-dominated, non-infective inflammatory skin disease.

3. Claims: 4, 6; 1 and 7-58 (partly)

Use of a pharmaceutical composition comprising azithromycin or derivatives thereof for the manufacture of a medicament for the treatment of neutrophil-dominated, non-infective inflammatory autoimmune disease.

4. Claims: 5; 1 and 7-58 (partly)

Use of a pharmaceutical composition comprising azithromycin or derivatives thereof for the manufacture of a medicament for the treatment of neutrophil-dominated, non-infective inflammatory intestinal disease.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

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